Department of the Navy Human Research Protection Program

Education and Training Policy for Research Ethics and the Responsible Conduct of Research

1. Purpose

To provide policy for Department of the Navy (DON) commands, personnel, and DON-supported institutions on how to meet Department of Defense and DON requirements for research ethics training.

This policy focuses on the requirements for human subject protection training and will be updated as additional policy on research ethics training is implemented.

2. Background

In response to a DoD-wide initiative to raise awareness of and improve compliance with human research protections, all Department of the Navy Human Research Protection Program (DON HRPP) personnel who conduct, review, approve, support, manage, or oversee research are required to complete initial and continuing research ethics training.

In 2000, the National Institutes of Health (NIH) implemented a training requirement for investigators and key personnel and established a program specific to NIH-supported research. The NIH also included training requirements for the responsible conduct of research (RCR) established under the auspices of the Office of Research Integrity (ORI) within the Department of Health and Human Services (DHHS).

3. Responsible Conduct of Research (RCR) Core Areas

The Public Health Service (PHS) policy for RCR outlines nine (9) core areas for initial and continuing education. These are referred to in DoDD 3216.2, "Protection of Human Subjects."

- a. Data acquisition, management, sharing and ownership
- b. Mentor/trainee responsibilities
- c. Publication practices and responsible authorship
- d. Peer review
- e. Collaborative science
- f. Human subjects
- g. Research involving animals
- h. Research misconduct
- i. Conflict of interest and commitment

4. DON Policy: Research Ethics Education Program Requirements

All personnel who conduct, review, approve, support, manage, or oversee research must complete initial training. All personnel then must complete three to six hours of research-ethics continuing training every three years, depending on their roles and responsibilities in human subject research.

To meet DON requirements for research ethics training, institutions may use their own institutional program or use existing programs that meet the requirements in this policy.

Whether institutions use already-available programs or create their own, the training program must meet the following requirements.

- a. Training programs must include initial and continuing programs.
- b. Content must be appropriate to the individuals' level of involvement and their duties and responsibilities.
- c. Program content, learning objectives, speaker qualifications, attendance, etc., must be documented clearly.
- d. Training programs must evaluate attendees' knowledge, learning, or meeting of the objectives.
- e. Attendees must have an opportunity to evaluate program content and speakers.
- f. Plans for continually evaluating and refining training needs.

The Collaborative Institutional Training Initiative (CITI), a web-based, self-contained course oriented to both biomedical and social behavioral research, meets these requirements. See enclosure (1). CITI also offers a number of training modules in several foreign languages through its international sites.

Commands are encouraged to provide annual education and training specific to their needs that supplements these requirements.

Note: The NIH web-based training program, "Human Participant Protections Education for Research Teams," does not meet DON HRPP training requirements as it is specific to NIH policies and procedures and has a biomedical focus.

5. Human Subject Protection Training Requirements by Role and Responsibility

a. <u>Initial Training</u>

All personnel who conduct, review, approve, support, manage, or oversee research must complete initial training. Individuals serving in several roles must complete the most comprehensive requirements. See enclosure (1) for specific training requirements and deadlines for completion.

b. Continuing Training

All personnel must complete three to six hours of research-ethics continuing training every three years depending on their roles and responsibilities in human subject research. Only training offerings directly relevant to research ethics, human subject protections, and the responsible conduct of research meet DON HRPP criteria for continuing training. Individuals may choose among many offerings to meet requirements. See enclosure (2).

6. Training Documentation

a. Individual Responsibility

Individuals are responsible for keeping accurate records of their initial and continuing training. PIs and key research personnel must provide verification or copies of training records when submitting research protocols.

b. <u>Institution Responsibility</u>

Institutions are responsible for verifying and storing training documents (electronic and/or paper copy). Institutions should verify whether PIs have met training requirements

prior to accepting research protocols for scientific or ethical review and whether all other personnel have met the training requirements appropriate to their role and level of responsibility.

c. **DON HRPP Responsibility**

DON HRPP maintains central electronic documentation for all personnel using the CITI program. The DON HRPP will monitor and oversee institutions' education and training programs.

7. References

- a. DoD Directive 3216.2, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," March 25, 2002
- b. SECNAVINST 3900.39D, "Human Research Protection Program," November 3, 2006
- c. National Institutes of Health (NIH) Notice: OD-00-039 of June 5, 2000 (Revised August 25, 2000)
- d. Office of Research Integrity, PHS Policy of Instruction in the Responsible Conduct of Research (RCR) December 1, 2000 (Pending)

Department of the Navy Human Research Protection Program Collaborative Institutional Training Initiative (CITI)

If institutions choose CITI for initial and continuing training, see below for requirements.

- After registering, individuals select the appropriate "Research Role" (Learner Group) and "Focus" (Course) of modules biomedical or social-behavioral research (SBR)
- Individuals must receive a score of 80% to receive a CITI-generated completion certificate.
- See CITI at https://www.citiprogram.org/default.asp

Research Role	Initial Training	Continuing Training
1. Navy Surgeon	BIOMEDICAL FOCUS	Continuing training requirement:
General (SG), Chief of	1. History & Ethical Principles	3 hours every 3 years
Naval Research (CNR)	2. Defining Research with Human Subjects – Social	
and Command	Behavioral Research (SBR)	Options:
Leadership	3. SBR for Biomedical Researchers	
(Institutional Signatory	4. Department of the Navy HRPP Module for Senior Navy	1. CITI Program: 3 modules of your
Officials, Commanding	and Command Leadership	choice from refresher modules or other
Officers , Executive		modules you have not taken
Officers, Officers-In-	SOCIAL-BEHAVIORAL FOCUS	
Charge)	1. History & Ethical Principles – SBR	2. Three (3) hours of equivalent continuing
Estimated Time: 1 hour	2. Defining Research with Human Subjects – SBR	training
	3. Assessing Risks - SBR	
Notes:	4. Department of the Navy HRPP Module for Senior Navy	
1. Individuals serving in	and Command Leadership	
several roles must		
complete the most		
comprehensive		
requirements.		
2. Individuals must		
complete the initial		
training requirements		
within 60 days of		
assignment.		

Research Role	Initial Training	Continuing Training
2. Directors,	BIOMEDICAL FOCUS	Continuing training requirement:
Department Chairs,	1. History & Ethical Principles	3 hours every 3 years
Program Managers, and	2. Defining Research with Human Subjects – SBR	
Office of Naval Research	3. SBR for Biomedical Researchers	Options:
(ONR) Department	4. Records –based Research	
Directors, Division	5. Genetic Research	1. CITI Program: 3 modules of your
Directors and Program	6. Research with Protected Populations – Overview	choice from refresher modules or other
Officers	7. Group Harms - Research with culturally or medically vulnerable groups	modules you have not taken
Estimated Time: 2 – 3	8. Privacy & Confidentiality – SBR	2. Three (3) hours of equivalent continuing
hours	9. Conflict of Interest	training
	10. Department of the Navy HRPP Module	
Notes:		
1. Individuals serving in	SOCIAL-BEHAVIORAL RESEARCH	
several roles must	1. History & Ethical Principles – SBR	
complete the most	2. Defining Research with Human Subjects – SBR	
comprehensive	3. Assessing Risks – SBR	
requirements.	4. Records-based Research	
	5. Research with Protected Populations – Overview	
2. Individuals must	6. Group Harms - Research with culturally or medically	
complete the initial	vulnerable groups	
training requirements	7. Privacy & Confidentiality – SBR	
within 60 days of	8. Conflict of Interest	
assignment.	9. Department of the Navy HRPP Module for COs	

Research Role	Initial Training	Continuing Training
3. Investigators, Key	BIOMEDICAL FOCUS	Continuing training requirement:
Research Personnel &	1. History & Ethical Principles	6 hours every 3 years
Medical Monitors	2. Defining Research with Humans - SBR	
	3. Basic IRB Regulations & Review Process	Options:
Estimated Time: 4 – 6	4. Informed Consent	
hours	5. SBR for Biomedical Researchers	1. CITI Program: 6 modules of your
	6. Assessing Risks – SBR	choice from refresher modules or other
Notes:	7. Records-based Research	modules you have not taken
1. Individuals serving in	8. Genetic Research	
several roles must	9. Research with Protected Populations – Overview	2. Six (6) hours of equivalent continuing
complete the most	10. Group Harms - Research with culturally or medically	training
comprehensive	vulnerable groups	
requirements.	11. Internet Research – SBR	
•	12. Privacy and Confidentiality - SBR	
2. All investigators, key	13. FDA-regulated research	
research personnel	14. Conflicts of Interest	
(principal investigators,	15. Hot Topics – No Quiz	
associate investigators,	16. Department of the Navy HRPP Module	
and all research personnel	·	
listed in the protocol), and	SOCIAL-BEHAVIORAL FOCUS (SBR)	
medical monitors must	1. History and Ethics – SBR	
complete the initial	2. The Regulations and SBR	
training requirement prior	3. Informed Consent - SBR	
to submitting new	4. Defining Research with Humans – SBR	
research protocols for	5. Assessing Risks – SBR	
review.	6. Records-based Research	
	7. Research with Protected Populations – Overview	
3. If associate	8. Group Harms - Research with culturally or medically	
investigators, key research	vulnerable groups	
personnel, or medical	9. Internet Research – SBR	
monitors have not	10. Privacy and Confidentiality – SBR	
completed the initial	11. Conflicts of Interest	
training requirement, new	12. Hot Topics – No Quiz	
research protocols will be	13. Department of Navy HRPP Module	CONTINUED ON NEXT PAGE
accepted for review, but	1	
final approval will be		

withheld until the training	
requirement has been met.	
Associate investigators,	
key research personnel,	
and medical monitors	
shall not participate in	
research activities until	
the initial training	
requirement has been met.	
1,	
4. Investigators	
conducting research with	
pregnant women,	
children, prisoners,	
workers, students, or	
employees must complete the related modules.	
the related modules.	

Research Role	Initial Training	Continuing Training
4. Scientific Review:	Each institution must determine its training requirements for	
Chair, Members, and	these individuals and describe the requirements in its policies	
Reviewers	and procedures.	
Estimated Time: 1 hour	The DON HRPP recommends the following modules: 1. History and Ethical Principles	
Note:	2. Defining Research with Human Subjects	
Individuals serving in several roles must	3. Department of the Navy HRPP Module	
complete the most		
comprehensive		
requirements.		

Research Role	Initial Training	Continuing Training
5. Institutional Review	BIOMEDICAL FOCUS	Continuing training requirement:
Board (IRB) Chairs,	1. History & Ethical Principles	6 hours every 3 years
Vice Chairs and	2. Defining Research with Humans - SBR	
Members	3. Basic IRB Regulations & Review Process	Options:
	4. Informed Consent	
Estimated Time: 4 – 6	5. SBR for Biomedical Researchers	1. CITI Program: 6 modules of your choice
hours	6. Assessing Risk – SBR	from refresher modules or other modules
	7. Records-based Research	you have not taken
Notes:	8. Genetic Research	
1. Individuals serving in	9. Research with Protected Populations – Overview	2. Six (6) hours of equivalent continuing
several roles must	10. Group Harms - Research with culturally or medically	training
complete the most	vulnerable groups	
comprehensive	11. Internet Research – SBR	
requirements.	12. Research with Prisoners – SBR	
	13. Research Involving Pregnant Women	
2. Individuals must	14. Research Involving Minors	
complete their initial	15. Research Involving Children- SBR	
training requirement prior	16. Privacy & Confidentiality – SBR	
to reviewing and voting on	17. Workers as Research Subjects	
research protocols.	18. FDA-regulated research	
_	19. Conflicts of Interest	
	20. IRB Member	
	21. Hot Topics – No quiz	
	22. Department of the Navy HRPP Module	
	SOCIAL-BEHAVIORAL FOCUS (SBR)	
	1. History and Ethics – SBR	
	2. The Regulations and SBR	
	3. Informed Consent - SBR	
	4. Defining Research with Humans – SBR	
	5. Assessing Risks – SBR	
	6. Records-based Research	
	7. Research with Protected Populations – Overview	
	8. Group Harms - Research with culturally or medically	
	vulnerable groups	CONTINUED ON NEXT PAGE
	9. Internet Research – SBR	

 10. Privacy and Confidentiality – SBR 11. Research with Prisoners – SBR 12. Research with Pregnant Women 13. Research with Children - SBR 14. Conflicts of Interest 15. IRB Member 16. Hot Topics – No Quiz 	
17. Department of Navy HRPP Module	

6. HRPP (including legal counsel directly supporting the HRPP) & 1. History & Ethical Principles 2. Defining Research with Humans - SBR 3. Basic IRB Regulations & Review Process 4. Informed Consent 5. SBR for Biomedical Researchers 6. Assessing Risk – SBR 7. Records-based Research 6. Assessing Risk – SBR 7. Records-based Research 8. Genetic Research 9. Individuals serving in several roles must complete the most comprehensive requirements. 1. Individuals must complete the initial training requirement within 30 days of assignment to their 1. History & Ethical Principles 6. hours every 3 years 0. Options: 1. CITI Program: 6 modules of your choice from refresher modules or other modules you have not taken 1. CITI Program: 6 modules or other modules you have not taken 2. Six (6) hours of equivalent continuing training requirement: 1. CITI Program: 6 modules or other modules you have not taken 2. Six (6) hours of equivalent continuing training training requirements 4 - 6 hours every 3 years 0. Options: 1. CITI Program: 6 modules or other modules you have not taken 2. Six (6) hours of equivalent continuing training. 1. Individuals you have not taken 2. Six (6) hours of equivalent continuing training. 1. Individuals with training 1. Research with Protected Populations – Overview 1. Internet Research – SBR 1. Research Involving Pregnant Women 1. Research Involving Minors 1. Search Involving Children- SBR 1. Research Involving Children- SBR 1. Research Involving Children- SBR 1. CITI Program: 6 modules of your choice from refresher modules or other modules or other modules you have not taken 2. Six (6) hours of equivalent continuing training. 1. CITI Program: 6 modules or other modules o	Research Role	Initial Training	Continuing Training
counsel directly supporting the HRPP) & 12. Defining Research with Humans - SBR 13. Basic IRB Regulations & Review Process 4. Informed Consent 5. SBR for Biomedical Researchers 6. Assessing Risk - SBR 7. Records-based Research 8. Genetic Research 8. Genetic Research 8. Genetic Research 9. Research with Protected Populations — Overview 10. Group Harms - Research with Prisoners — SBR 12. Research involving Pregnant Women 14. Research Involving Minors requirements within 30 days of assignment to their positions. 15. Research Involving Minors 18. Research 19. Conflicts of Interest 20. IRB Member 21. Hot Topics — No quiz 22. Department of the Navy HRPP Module 15. GCIAL-BEHAVIORAL FOCUS 1. History and Ethics — SBR 2. The Regulations and SBR 3. Informed Consent - SBR 4. Defining Research with Humans — SBR 5. Assessing Risks — SBR 6. Records-based Research 9.	6. HRPP (including legal	BIOMEDICAL FOCUS	
supporting the HRPP) & IRB staff IRB staff IRB staff IRB staff IRB staff IRB staff IRB staff IRB staff IRB staff IRB staff IRB staff IRB staff	counsel directly	1. History & Ethical Principles	
4. Informed Consent 5. SBR for Biomedical Researchers 6. Assessing Risk – SBR 7. Records-based Research 8. Genetic Research 1. Individuals serving in several roles must complete the most comprehensive requirements. 2. Individuals must complete the initial training requirements within 30 days of assignment to their positions. 2. Individuals must complete the initial training requirements within 30 days of assignment to their positions. 4. Informed Consent – SBR 7. Records-based Research 8. Genetic Research 9. Research with Protected Populations – Overview standard to requirements within 30 days of assignment to their positions. 4. Informed Consent – SBR 7. Records-based Research with culturally or medically vulnerable groups 11. Internet Research – SBR 12. Research Involving Pregnant Women 14. Research Involving Minors 15. Research Involving Children- SBR 16. Research Involving Children- SBR 17. Workers as Research 19. Conflicts of Interest 20. IRB Member 21. Hot Topics – No quiz 22. Department of the Navy HRPP Module SOCIAL-BEHAVIORAL FOCUS 1. History and Ethics – SBR 2. The Regulations and SBR 3. Informed Consent - SBR 4. Defining Research with Humans – SBR 5. Assessing Risks – SBR 6. Records-based Research	supporting the HRPP) &	2. Defining Research with Humans - SBR	Options:
S. SBR for Biomedical Researchers	IRB staff	3. Basic IRB Regulations & Review Process	1. CITI Program: 6 modules of your
hours 6. Assessing Risk – SBR 7. Records-based Research 8. Genetic Research 9. Research with Protected Populations – Overview 10. Group Harms - Research with culturally or medically vulnerable groups 11. Internet Research – SBR 12. Research with Prisoners – SBR 13. Research Involving Pregnant Women 14. Research Involving Minors 15. Research SBR 16. Privacy & Confidentiality – SBR 17. Workers as Research SBR 18. FDA-regulated research 19. Conflicts of Interest 20. IRB Member 21. Hot Topics – No quiz 22. Department of the Navy HRPP Module SOCIAL-BEHAVIORAL FOCUS 1. History and Ethics – SBR 2. The Regulations and SBR 3. Informed Consent - SBR 4. Defining Research 5. Assessing Risk – SBR 6. Records-based Research 2. Six (6) hours of equivalent continuing training. 2. Six (6) hours of equivalent continuing training.		4. Informed Consent	choice from refresher modules or other
Notes: 1. Individuals serving in several roles must complete the most comprehensive requirements. 2. Individuals must complete the initial training requirements within 30 days of assignment to their positions. 1. Records-based Research 2. Research with Protected Populations – Overview 10. Group Harms - Research with culturally or medically vulnerable groups 11. Internet Research – SBR 12. Research involving Pregnant Women 14. Research Involving Pregnant Women 14. Research Involving Children- SBR 16. Privacy & Confidentiality – SBR 17. Workers as Research Subjects 18. FDA-regulated research 19. Conflicts of Interest 20. IRB Member 21. Hot Topics – No quiz 22. Department of the Navy HRPP Module SOCIAL-BEHAVIORAL FOCUS 1. History and Ethics – SBR 2. The Regulations and SBR 3. Informed Consent - SBR 4. Defining Research with Humans – SBR 5. Assessing Risks – SBR 6. Records-based Research 2. Six (6) hours of equivalent continuing training. 2. Six (6) hours of equivalent continuing training.	Estimated Time: 4 – 6	5. SBR for Biomedical Researchers	modules you have not taken
Notes: 1. Individuals serving in several roles must complete the most comprehensive requirements. 2. Individuals must complete the initial training requirements within 30 days of assignment to their positions. 8. Genetic Research 9. Research with Protected Populations – Overview 10. Group Harms - Research with culturally or medically vulnerable groups 11. Internet Research – SBR 12. Research Involving Pregnant Women 14. Research Involving Minors 15. Research Involving Children- SBR 16. Privacy & Confidentiality – SBR 17. Workers as Research Subjects 18. FDA-regulated research 19. Conflicts of Interest 20. IRB Member 21. Hot Topics – No quiz 22. Department of the Navy HRPP Module SOCIAL-BEHAVIORAL FOCUS 1. History and Ethics – SBR 2. The Regulations and SBR 3. Informed Consent - SBR 4. Defining Research with Humans – SBR 5. Assessing Risks – SBR 6. Records-based Research	hours	6. Assessing Risk – SBR	
1. Individuals serving in several roles must complete the most comprehensive requirements. 2. Individuals must complete the initial training requirements within 30 days of assignment to their positions. 13. Research Involving Pregnant Women 14. Research Involving Minors 15. Research Involving Children- SBR 16. Privacy & Confidentiality – SBR 17. Workers as Research Subjects 18. FDA-regulated research 19. Conflicts of Interest 20. IRB Member 21. Hot Topics – No quiz 22. Department of the Navy HRPP Module SOCIAL-BEHAVIORAL FOCUS 1. History and Ethics – SBR 2. The Regulations and SBR 3. Informed Consent - SBR 4. Defining Research with Protected Populations – Overview 10. Group Harms - Research with culturally or medically vulnerable groups 11. Internet Research – SBR 12. Research Involving Pregnant Women 14. Research Involving Children- SBR 16. Privacy & Confidentiality – SBR 17. Workers as Research Subjects 18. FDA-regulated research 19. Conflicts of Interest 20. IRB Member 21. Hot Topics – No quiz 22. Department of the Navy HRPP Module		7. Records-based Research	2. Six (6) hours of equivalent continuing
10. Group Harms - Research with culturally or medically vulnerable groups 11. Internet Research – SBR 12. Individuals must complete the initial training requirements within 30 days of assignment to their positions. 13. Research Involving Pregnant Women 14. Research Involving Minors 15. Research Involving Children- SBR 16. Privacy & Confidentiality – SBR 17. Workers as Research Subjects 18. FDA-regulated research 19. Conflicts of Interest 20. IRB Member 21. Hot Topics – No quiz 22. Department of the Navy HRPP Module SOCIAL-BEHAVIORAL FOCUS 1. History and Ethics – SBR 2. The Regulations and SBR 3. Informed Consent - SBR 4. Defining Research with Humans – SBR 5. Assessing Risks – SBR 6. Records-based Research	Notes:	8. Genetic Research	training.
the most comprehensive requirements. 2. Individuals must complete the initial training requirements within 30 days of assignment to their positions. 13. Research Involving Pregnant Women 14. Research Involving Minors 15. Research Involving Children-SBR 16. Privacy & Confidentiality – SBR 17. Workers as Research Subjects 18. FDA-regulated research 19. Conflicts of Interest 20. IRB Member 21. Hot Topics – No quiz 22. Department of the Navy HRPP Module SOCIAL-BEHAVIORAL FOCUS 1. History and Ethics – SBR 2. The Regulations and SBR 3. Informed Consent - SBR 4. Defining Research with Humans – SBR 6. Records-based Research 6. Records-based Research	1. Individuals serving in	9. Research with Protected Populations – Overview	
11. Internet Research – SBR 2. Individuals must complete the initial training requirements within 30 days of assignment to their positions. 12. Research Involving Pregnant Women 13. Research Involving Minors 14. Research Involving Children- SBR 16. Privacy & Confidentiality – SBR 17. Workers as Research Subjects 18. FDA-regulated research 19. Conflicts of Interest 20. IRB Member 21. Hot Topics – No quiz 22. Department of the Navy HRPP Module SOCIAL-BEHAVIORAL FOCUS 1. History and Ethics – SBR 2. The Regulations and SBR 3. Informed Consent – SBR 4. Defining Research with Humans – SBR 5. Assessing Risks – SBR 6. Records-based Research	several roles must complete	10. Group Harms - Research with culturally or medically	
2. Individuals must complete the initial training requirements within 30 days of assignment to their positions. 12. Research Involving Pregnant Women 14. Research Involving Minors 15. Research Involving Children- SBR 16. Privacy & Confidentiality – SBR 17. Workers as Research Subjects 18. FDA-regulated research 19. Conflicts of Interest 20. IRB Member 21. Hot Topics – No quiz 22. Department of the Navy HRPP Module SOCIAL-BEHAVIORAL FOCUS 1. History and Ethics – SBR 2. The Regulations and SBR 3. Informed Consent - SBR 4. Defining Research with Humans – SBR 5. Assessing Risks – SBR 6. Records-based Research	the most comprehensive	vulnerable groups	
2. Individuals must complete the initial training requirements within 30 days of assignment to their positions. 13. Research Involving Pregnant Women 14. Research Involving Minors 15. Research Involving Children- SBR 16. Privacy & Confidentiality – SBR 17. Workers as Research Subjects 18. FDA-regulated research 19. Conflicts of Interest 20. IRB Member 21. Hot Topics – No quiz 22. Department of the Navy HRPP Module SOCIAL-BEHAVIORAL FOCUS 1. History and Ethics – SBR 2. The Regulations and SBR 3. Informed Consent - SBR 4. Defining Research with Humans – SBR 5. Assessing Risks – SBR 6. Records-based Research	requirements.	11. Internet Research – SBR	
complete the initial training requirements within 30 days of assignment to their positions. 14. Research Involving Minors 15. Research Involving Children- SBR 16. Privacy & Confidentiality – SBR 17. Workers as Research Subjects 18. FDA-regulated research 19. Conflicts of Interest 20. IRB Member 21. Hot Topics – No quiz 22. Department of the Navy HRPP Module SOCIAL-BEHAVIORAL FOCUS 1. History and Ethics – SBR 2. The Regulations and SBR 3. Informed Consent - SBR 4. Defining Research with Humans – SBR 5. Assessing Risks – SBR 6. Records-based Research		12. Research with Prisoners – SBR	
requirements within 30 days of assignment to their positions. 15. Research Involving Children- SBR 16. Privacy & Confidentiality – SBR 17. Workers as Research Subjects 18. FDA-regulated research 19. Conflicts of Interest 20. IRB Member 21. Hot Topics – No quiz 22. Department of the Navy HRPP Module SOCIAL-BEHAVIORAL FOCUS 1. History and Ethics – SBR 2. The Regulations and SBR 3. Informed Consent - SBR 4. Defining Research with Humans – SBR 5. Assessing Risks – SBR 6. Records-based Research	2. Individuals must	13. Research Involving Pregnant Women	
of assignment to their positions. 16. Privacy & Confidentiality – SBR 17. Workers as Research Subjects 18. FDA-regulated research 19. Conflicts of Interest 20. IRB Member 21. Hot Topics – No quiz 22. Department of the Navy HRPP Module SOCIAL-BEHAVIORAL FOCUS 1. History and Ethics – SBR 2. The Regulations and SBR 3. Informed Consent - SBR 4. Defining Research with Humans – SBR 5. Assessing Risks – SBR 6. Records-based Research	complete the initial training	14. Research Involving Minors	
positions. 17. Workers as Research Subjects 18. FDA-regulated research 19. Conflicts of Interest 20. IRB Member 21. Hot Topics – No quiz 22. Department of the Navy HRPP Module SOCIAL-BEHAVIORAL FOCUS 1. History and Ethics – SBR 2. The Regulations and SBR 3. Informed Consent - SBR 4. Defining Research with Humans – SBR 5. Assessing Risks – SBR 6. Records-based Research	requirements within 30 days	15. Research Involving Children- SBR	
18. FDA-regulated research 19. Conflicts of Interest 20. IRB Member 21. Hot Topics – No quiz 22. Department of the Navy HRPP Module SOCIAL-BEHAVIORAL FOCUS 1. History and Ethics – SBR 2. The Regulations and SBR 3. Informed Consent - SBR 4. Defining Research with Humans – SBR 5. Assessing Risks – SBR 6. Records-based Research	of assignment to their	16. Privacy & Confidentiality – SBR	
19. Conflicts of Interest 20. IRB Member 21. Hot Topics – No quiz 22. Department of the Navy HRPP Module SOCIAL-BEHAVIORAL FOCUS 1. History and Ethics – SBR 2. The Regulations and SBR 3. Informed Consent - SBR 4. Defining Research with Humans – SBR 5. Assessing Risks – SBR 6. Records-based Research	positions.	17. Workers as Research Subjects	
20. IRB Member 21. Hot Topics – No quiz 22. Department of the Navy HRPP Module SOCIAL-BEHAVIORAL FOCUS 1. History and Ethics – SBR 2. The Regulations and SBR 3. Informed Consent - SBR 4. Defining Research with Humans – SBR 5. Assessing Risks – SBR 6. Records-based Research		1	
21. Hot Topics – No quiz 22. Department of the Navy HRPP Module SOCIAL-BEHAVIORAL FOCUS 1. History and Ethics – SBR 2. The Regulations and SBR 3. Informed Consent - SBR 4. Defining Research with Humans – SBR 5. Assessing Risks – SBR 6. Records-based Research			
22. Department of the Navy HRPP Module SOCIAL-BEHAVIORAL FOCUS 1. History and Ethics – SBR 2. The Regulations and SBR 3. Informed Consent - SBR 4. Defining Research with Humans – SBR 5. Assessing Risks – SBR 6. Records-based Research			
SOCIAL-BEHAVIORAL FOCUS 1. History and Ethics – SBR 2. The Regulations and SBR 3. Informed Consent - SBR 4. Defining Research with Humans – SBR 5. Assessing Risks – SBR 6. Records-based Research		21. Hot Topics – No quiz	
 History and Ethics – SBR The Regulations and SBR Informed Consent - SBR Defining Research with Humans – SBR Assessing Risks – SBR Records-based Research 		22. Department of the Navy HRPP Module	
 History and Ethics – SBR The Regulations and SBR Informed Consent - SBR Defining Research with Humans – SBR Assessing Risks – SBR Records-based Research 			
 History and Ethics – SBR The Regulations and SBR Informed Consent - SBR Defining Research with Humans – SBR Assessing Risks – SBR Records-based Research 		SOCIAL-BEHAVIORAL FOCUS	
2. The Regulations and SBR 3. Informed Consent - SBR 4. Defining Research with Humans – SBR 5. Assessing Risks – SBR 6. Records-based Research			
3. Informed Consent - SBR 4. Defining Research with Humans – SBR 5. Assessing Risks – SBR 6. Records-based Research		1	
 4. Defining Research with Humans – SBR 5. Assessing Risks – SBR 6. Records-based Research 		1	
5. Assessing Risks – SBR6. Records-based Research			
6. Records-based Research			
		1	
		7. Research with Protected Populations – Overview	CONTINUED ON NEXT PAGE
8. Group Harms - Research with culturally or medically		_	
vulnerable groups			

O Intermed Decreed CDD	
9. Internet Research – SBR	
10. Privacy and Confidentiality – SBR	
11. Research with Prisoners – SBR	
12. Research with Pregnant Women	
13. Research with Children - SBR	
14. Conflicts of Interest	
15. IRB Member	
16. Hot Topics – No Quiz	
17. Department of the Navy HRPP Module	

Research Role	Initial Training	Continuing Training
7. Research Coordinators,	BIOMEDICAL FOCUS	Continuing training requirement:
Clinical Coordinators,	1. History & Ethical Principles	6 hours every 3 years
Study Coordinators &	2. Defining Research with Humans - SBR	
Research Administrators	3. Basic IRB Regulations & Review Process	Options:
	4. Informed Consent	1. CITI Program: 6 modules of your
Estimated Time: 4 – 6	5. SBR for Biomedical Researchers	choice from refresher modules or other
hours	6. Assessing Risk – SBR	modules you have not taken
	7. Records-based Research	
Notes:	8. Genetic Research	2. Six (6) hours of equivalent continuing
1. Individuals serving in	9. Research with Protected Populations – Overview	training.
several roles must complete	10. Group Harms - Research with culturally or medically	
the most comprehensive	vulnerable groups	
requirements.	11. Internet Research – SBR	
-	12. Research Involving Pregnant Women	
2. Individuals must	13. Research Involving Minors	
complete the initial training	14. Research Involving Children- SBR	
requirements within 30 days	15. Privacy & Confidentiality – SBR	
of assignment to their	16. Workers as Research Subjects	
positions.	17. FDA-regulated research	
	18. Conflicts of Interest	
	19. Hot Topics – No quiz	
	20. Department of the Navy HRPP Module	
	SOCIAL-BEHAVIORAL FOCUS	
	1. History and Ethics – SBR	
	2. The Regulations and SBR	
	3. Informed Consent - SBR	
	4. Defining Research with Humans – SBR	
	5. Assessing Risks – SBR	
	6. Records-based Research	
	7. Research with Protected Populations – Overview	
	8. Group Harms - Research with culturally or medically	
	vulnerable groups	CONTINUED ON NEXT PAGE
	9. Internet Research – SBR	
	10. Privacy and Confidentiality – SBR	

11. Research with Pregnant Women	
12. Research with Children - SBR13. Conflicts of Interest	
14. Hot Topics – No Quiz	
15. Department of the Navy HRPP Module	

Research Role	Initial Training	Continuing Training
8. Research Support	Each institution must determine its training requirements	
Personnel	for these individuals and describe the requirements in its policies and procedures.	
Estimated Time: 1 hour		
Notes: 1. Individuals serving in several roles must complete the most comprehensive requirements.	The DON HRPP recommends the following modules: 1. History and Ethical Principles 2. Defining Research with Human Subjects 3. Department of the Navy HRPP Module 4. Other modules, as appropriate, based on their role in research	
2. Research personnel are those who conduct clinical or research procedures; provide support to review committees; are responsible for access and release of private identifiable information, e.g., medical records personnel, information system personnel, individuals conducting procedures (laboratory, pharmacy, and radiology), legal counsel, grants and contracts personnel, privacy officers.		
3. Individuals must complete the initial training requirements within 30 days of assignment to their positions.		

Research Role	Initial Training	Continuing Training
9. DON-supported Extramural Performers Note:	All individuals conducting DON-supported extramural research must complete training that is equivalent to DON HRPP requirements prior to initiating work involving human subjects.	All individuals conducting DON-supported extramural research must complete continuing training that is equivalent to DON HRPP requirements.
The NIH web-based training program, "Human Participant Protections Education for Research Teams," is not adequate to	a) If an institution does not have training requirements, its personnel must follow DON HRPP requirements (4 – 6 hours). Register as Principal Investigator.	a) If an institution does not have continuing training requirements, its personnel must follow DON HRPP requirements.
meet DON HRPP training requirements.	b) If an institution uses the CITI to meet its training requirements, its personnel also must complete the DON-specific module (15 minutes). Register as DON-supported Extramural Performer.	b) If an institution uses the CITI to meet its continuing training requirements, its personnel also must complete the DON-specific module.
	c) If an institution's training requirement is not equivalent to DON requirements or CITI, its personnel must follow DON HRPP requirements (4 – 6 hours). Register as Principal Investigator.	c) If an institution's continuing training requirement is not equivalent to DON requirements or CITI, its personnel must follow DON HRPP requirements.

Department of Navy Human Research Protection Program Continuing Education and Training Options

Individuals may choose continuing training from among the following options. This list is not meant to be all encompassing.

- 1. CITI Continuing Training Modules (see enclosure (1)).
- 2. The following organizations and agencies, among others, sponsor programs that meet DON HRPP continuing training requirements.
 - a. DON HRPP
 - b. Department of Defense, U. S. Army and U. S. Air Force
 - c. Applied Research Ethics National Association (ARENA)
 - d. Society of Research Administrators (SRA) International
 - e. Office of Research Integrity (ORI)
 - f. Office of Human Research Protections (OHRP)
 - g. Food and Drug Administration (FDA)
 - h. Public Responsibility in Medicine and Research (PRIM&R)
 - i. Other institution's programs
- 3. The Poynter Center, Kennedy Institute, among others, sponsor courses, ethics symposia, and seminars that meet the continuing training requirement.
- 4. Several professional journals provide home-study programs.
- 5. Book: *Protecting Study Volunteers in Research*, Cynthia Dunn, M.D. and Gary Chadwick, PharmD., M.P.H., C. I. P. Continuing education credits for physicians, nurses, and other health-care professionals are available.